510(k) Summary

JUN 10 2008

Vertebral Technologies, Inc.

InterFuse™ Intervertebral Body Fusion Device

510(k) Notification K080673

MANUFACTURER INFORMATION

Name & Address: Vertebral Technologies, Inc. (VTI)
5909 Baker Road, Suite 550
Minnetonka, MN 55345 USA

Summary Prepared: March 7, 2008

Contact: Philip B. Jarvi
Vice President, Q.A. / Regulatory Affairs
952-912-5400 phone
952-912-5410 fax

DEVICE INFORMATION

Trade Name: InterFuse™ Intervertebral Body Fusion Device (IFD)

Classification Name: 21CFR 888.3080 – Intervertebral Fusion Device with Bone Graft, Lumbar

Product Code: MAX

Common / Usual Name: Intervertebral Body Fusion Device

Substantial equivalence: The Vertebral Technologies, Inc (VTI) *InterFuse™ Intervertebral Body Fusion Device* is substantially equivalent to FDA approved predicate devices with regard to materials, technological characteristics, indications for use and surgical techniques. These predicate devices are:

Zimmer / Spine Tech; BAK Vista - (P95002)

Synthes Spine; SynFix™-LR - (K072253)

RSB Spine; InterPlate - (K071922)

Device Description:

VTI's IFD device is made of PEEK, a polymer with a history of use in interbody fusion device designs, and which has modulus similar to bone. Each segment of the device has embedded metal beads (tantalum) that aid in visualizing the implanted device under x-ray and to aid in position retention when assembled in the disc space. Each segment has an integral rail and / or slot which slides through the rail or slot in the adjacent segment to complete the device. Each segment incorporates a stop to help ensure that it is properly aligned with the adjacent segment. The exposed rail of each segment is removed after the adjacent segment is installed. The modular system allows for as few as three segments to be used, although most patients will require between four and six segments for optimum coverage of the vertebral end plate. Each segment has a vertical slot through the device for the surgeon to fill with autogenous bone that will provide a path for solid bone growth during the fusion process. The device is produced in four heights and two anterior-posterior dimensions to fit a range of potential disc spaces. The device will also be produced in flat and angled (lordotic) shapes to fit the angular geometry of the disc at each disc level.

Intended Use:

The InterFuse™ Intervertebral Body Fusion Device is indicated for intervertebral spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). The InterFuse device is to be used in patients who have had at least six (6) months of non-operative treatment. These patients may have had a previous non-fusion surgery at the involved spinal level(s). The InterFuse device is indicated for use with autogenous bone graft, and to be used with supplemental internal spinal fixation systems that have been cleared for use by the FDA in the lumbosacral spine.

Substantial Equivalence: The VTI InterFuse™ IFD is substantially equivalent to FDA approved predicate devices with regard to indications for use, materials, technological characteristics and surgical techniques. The InterFuse™ IFD offers no additional risks to the patient and the materials and manufacturing methods add no new or additional safety concerns. The InterFuse™ IFD, as well as the predicates, is submitted without clinical information. The substantially equivalent predicate devices are:

Zimmer / Spine Tech; BAK Vista - (P95002)
Synthes Spine; SynFix™-LR - (K072253)
RSB Spine; InterPlate - (K071922)

Testing: The InterFuse™ Implant has been developed, verified and validated in compliance with a comprehensive design process. The corresponding Bench Testing has been accomplished according to a Master Test Plan for the device. The test plan shows the required test, the source of the requirement, the protocol and the report. If the method is from a standard, the voluntary standard is referenced.

The bench testing has demonstrated the physical attributes and durability of the InterFuse™ IFD by load deflection, cyclic fatigue resistance, material consistency and stability and processing control. Cadaver testing has verified the surgical technique and instrument performance. Bench testing and cadaver evaluations have also verified the desired performance requirements of device stability, as defined by the resistance of the device to expulsion from the disc space or disassembly in the joint space and resistance to subsidence.

The InterFuse™ IFD also demonstrated that it meets internationally recognized standards for biocompatibility (ISO 10993) and sterility (EN550).

Clinical testing was not used to determine substantial equivalence.

Summary: Based on the evidence of substantial equivalence the InterFuse™ IFD is considered to be safe and effective and will perform as well or better than the referenced predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 10 2008

Vertebral Technologies, Incorporated
% Philip B. Jarvi and Associates
Mr. Philip B. Jarvi
Vice President, Quality Assurance/Regulatory Affairs
14289 Yellowpine
Andover, Minnesota 55304

Re: K080673
Trade/Device Name: InterFuse™ Intervertebral Body Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: II
Product Code: MAX
Dated: March 07, 2008
Received: March 12, 2008

Dear Mr. Jarvi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080673

Device Name: InterFuse™ Intervertebral Body Fusion Device

Indications for Use:

The InterFuse™ Intervertebral Body Fusion Device is indicated for intervertebral spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). The InterFuse device is to be used in patients who have had at least six (6) months of non-operative treatment. These patients may have had a previous non-fusion surgery at the involved spinal level(s). The InterFuse device is indicated for use with autogenous bone graft, and to be used with supplemental internal spinal fixation systems that have been cleared for use by the FDA in the lumbosacral spine.

Prescription Use _Yes_ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use __No__ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for mem

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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